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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,078	04/25/2001	Olivier De Lacharriere	016800-438	6852

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EXAMINER	
WELLS, LAUREN Q	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,078	LACHARRIERE ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,20 and 23-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,20 and 23-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/580,291.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 19-20 and 23-37 are pending. The response and declaration filed 5/25/04, are persuasive to show that TNF-alpha and interleukin-1 antagonists were well established in the art prior to December 28, 1994, the effective filing date of the instant application. The 35 USC 112, 1st paragraph, rejection in the previous Office Action is hereby overcome.

Claim Rejections - 35 USC § 112

Claims 19-20, 23-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrases "composition comprising. . .at least one agent. . .utilized in a composition that does not include a TNF-alpha antagonist. . .an amount of at least one TNF-alpha antagonist" in claim 19 (lines 3-7) and, "composition comprising. . .at least one agent. . .utilized in a composition that does not include an interleukin-1 antagonist or a TNF-alpha antagonist. . .an amount of at least one interleukin-1 antagonist and at least one TNF-alpha antagonist" in claim 20, are vague and indefinite, as they are confusing. For example in claim 19, the instant invention claims a composition comprising an agent that elicits an irritant side effect and a TNF-alpha antagonist. However, the claim also recites that the agent that elicits an irritant side effect cannot be in a composition with a TNF-alpha antagonist. This is confusing, as the claim recites a composition with and without a TNF alpha antagonist. For this reason, it is not clear what the instant composition comprises or conversely, does not comprise. The same logic applies to claim 20.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-20, 23-25, 27-28, 30-33, 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Gallina (4,514,384).

Gallina exemplify a composition comprising 10% benzoyl peroxide (effective amount of agent to elicit an irritant side effect), 1% hydrocortisone alcohol (amount of IL-1 and TNF-alpha antagonists sufficient to eliminate or alleviate irritant side effect), 39.17% polyvinylpyrrolidone (histamine antagonist—heterocycle)), 0.5% methylparaben (antibacterial/antifungal), and glycerine and olive oil (acceptable medium), see Col. 4, lines 41-50. For the composition in the form of solid, gel, paste, cream, salve, ointment, liquid, and powder, see Col. 4 ,lines 57-59.

It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 103

Claims 26, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallina as applied to claims 19-20, 23-25, 27-28, 30-33, 35-36 above, and further in view of Dubash et al. (4,383,986).

Gallina is applied as discussed above. The reference lacks a preferred amount of antagonist.

Dubash et al. teach hemorrhoidal compositions comprising hydrocortisone as active ingredients, wherein 0.001-0.5% is taught as a therapeutically effective amount of hydrocortisone. See title, abstract, Col. 2, lines 21-35. .

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the hydrocortisone of Gallina as comprising 0.001-0.1% of the composition, as taught by Dubash et al., a) because Gallina and Dubash et al. are both directed toward compositions comprising hydrocortisone as active ingredients for treating hemorrhoids, and Dubash et al. teach 0.001-0.1% as a therapeutically effective amount of hydrocortisone for the treatment of hemorrhoids; b) because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 29, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallina as applied to claims 19-20, 23-25, 27-28, 30-33, 35-36 above, and further in view of Allen (4,895,727)

Gallina is applied as discussed above. Lidocaine is taught as a topical anesthetic that can be added to the composition. The reference lacks lidocaine hydrochloride.

Allen teaches lidocaine and lidocaine hydrochloride as equivalent anesthetic agents, see Col. 5, lines 56-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the lidocaine of Gallina as lidocaine hydrochloride, as taught by Allen, because of the expectation of achieving equivalent anesthetics.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER